NATIONAL MARROW DONOR PROGRAM®

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April 28, 2014

LCDR Christopher Steele
Office of Naval Research
Code 34 – Warfighter Performance
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: **Quarterly Performance/Technical Report of the National Marrow Donor Program®**

Reference: Grant Award #N00014-13-1-0039 between the Office of Naval Research and the National Marrow Donor Program

Dear LCDR. Steele:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of January 1, 2014 to March 31, 2014.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention at 612-362-3403 or at cabler@nmdp.org.

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Contracts Manager

Enclosure: Quarterly Report with SF298

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14. ABSTRACT
1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation: Create a platform that facilitates multicenter collaboration and data management.

15. SUBJECT TERMS
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Grant Award N00014-13-1-0039

DEVELOPMENT OF MEDICAL TECHNOLOGY FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS

QUARTERLY PERFORMANCE / TECHNICAL REPORT

FOR

JANUARY 01, 2014 to MARCH 31, 2014

PERIOD 5

Office of Naval Research

And

The National Marrow Donor Program
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QUARTER PROGRESS REPORT

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

January 01, 2014 through March 31, 2014

TABLE OF CONTENTS

IIA. Contingency Preparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians

IIA.1 Task 1: *Maintain the Radiation Injury Treatment Network (RITN) to prepare for the care of patients resulting from a hematopoietic toxic event.*

Period 5 Activity:

- Continued to coordinate with the Association of State and Territorial Health Officials on the project to determine the distribution process for the last mile (to get the medication into the hands of the appropriate people to administer to the correct responders or casualties) of the medical countermeasure G-CSF (Neupogen) following a mass casualty radiological incident.

IIA.1 Task 2: *GCSF in Radiation Exposure – This task is closed.*

IIA.1 Task 3: *Patient Assessment Guidelines and System Enhancements – This task is closed*

IIA 1 Task 4: *National Data Collection Model – This task is closed.*

IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.

IIA.2 Task 1: *Ensure NMDP maintains effective plans to continue critical facility and staff-related functions as a result of operations interruption events.*

Period 5 Activity:

- Purchasing small equipment (high quality power strips) to facilitate Operations staff's ability to continue to work during a power outage by increasing the number of outlets available with generator power.

IIA.2 Task 2: *Sibling Typing Standard Operating Procedures – This task is closed*

IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.

IIA.3 Task 1: *I.S. Disaster Recovery – This task is closed.*

IIA.3 Task 2: *Critical Facility and Staff Related Functions – This task is closed.*

IIB. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.

IIB.1 Task 1: *Expand the genetic diversity of the Registry through continued addition of adult donors and cord blood units, utilizing high volume HLA typing methodologies.*

Period 5 Activity:

- No activity this period.

IIB.1 Task 2: *Evaluate HLA-DRB1 High Res typing – This task is closed.*

IIB.1 Task 3: *Evaluate HLA-C Typing of Donors – This task is closed*

IIB.1 Task 4: *Evaluate the suitability of buccal swabs as a method to collect DNA samples to HLA type casualties and potential related donors in contingency situations, and to obtain research samples.*

Period 5 Activity:

Frozen Buccal Swab Study:

- The study will compare swabs stored at room temperature and -30°C, for quality of DNA, quantity of DNA, and high resolution HLA characterization, at selected time points over multiple years.
- Sample collection with assigned storage condition from volunteer QC donors is almost complete. Upon finalizing a service agreement with a lab that will perform NGS (Next Generation Sequencing) typing methodology, the final collection for the freshest possible baseline samples will commence.

IIB 1 Task 5: *Evaluate the factors of donor utilization and speed of search process after strategic upgrading of selected adult volunteer donors.*

Period 5 Activity:

- No activity this period.

IIB 1 Task 6: *Maintain a comprehensive quality control program.*

Period 5 Activity:

Genomic DNA Swabs:

- Work continued on the study to assess the feasibility of using purified genomic DNA as an alternative QC sample type, in order to decrease the cost and increase allelic diversity of the QC program.
    - Following successful typing results from phase II of the pilot study, the purified DNA samples created for phase III of the study were incorporated into the regular recruitment and customized shipments to confirm all the contract HLA laboratories could accurately type blind purified QC samples from the 2 DNA extraction labs identified as alternative vendors. All labs successfully typed QC samples from both extraction labs without repeats.
        - The results of the technical analysis revealed the laboratory originally selected to perform the DNA extractions on the stored frozen whole blood during phase I of the pilot study had superior DNA yields, as well as the most competitive price.
    - The final phase of this pilot study was to select 5 distinct volunteer QC donors and obtain fresh blood, to assess whether DNA yield is impacted by sample age or freeze/thaw cycles.
        - Five ml of fresh blood, fresh frozen blood, and existing frozen blood inventory were sent to the DNA extraction lab for quantitative and qualitative DNA analysis. Based on a small sample size of n=5, no significant difference in yield between the 3 blood sample types for any donor was observed.
        - Based on the results of the study, existing volunteer QC donors with stored repository blood aliquots will be selected for DNA extraction for inclusion in the NMDP buccal swab QC program as a substitution to B-LCL swabs.

IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.
IIB 2 Task 1: *Ongoing collection of primary data for validation and storage in the Registry database.*
Period 5 Activity: • No activity this period.
IIB 2 Task 2: *Validation of Logic of Primary Data – This task is closed.*
IIB 2 Task 3: *Reinterpretation of Primary Data – This Task has been merged with Task IIB2.4.*
IIB 2 Task 4: *Interpretation of the primary data into genotype lists and integration into matching algorithm to optimize placement of donors onto patient searches.*
Period 5 Activity: • No activity this period.

IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.
IIB.3 Task 1: *Incorporate HLA allele and haplotype frequencies into matching algorithm.*
Period 5 Activity: • No activity this period.
IIB 3 Task 2: *Continue to enhance the allele and haplotype frequency data to include additional loci and increased resolution for ethnic groups with input from consultants with expertise in population genetics.*
Period 5 Activity: • No activity this period.

IIB 3 Task 3: *Cord Blood and Adult Donor Matching Benchmarks and Registry Modeling.*
Period 5 Activity: • No activity this period.
IIB 3 Task 4: *Couple haplotype prediction methodology with donor demographic data to target recruitment to areas populated by individuals with underrepresented HLA phenotypes.*
Period 5 Activity: • No activity this period.
IIB 3 Task 5: *Develop a bioinformatics web site for frequency information.*
Period 5 Activity: • No activity this period.
IIB 3 Task 6: *Use NMDP's expert Search Strategy Advisors as resources to further improve the matching algorithm and donor/cord blood identification software applications with the goal to maximize the ability of the software to identify the best donors/cords for each patient.*
Period 5 Activity: • No activity this period.
IIB 3 Task 7: *Population Genetics – This task was merged with Task IIB3.2*
IIB 3 Task 8: *Haplotype Matching – This task was merged with Task IIB3.2*
IIB 3 Task 9: *Global Haplotype/Benchmark – This task was merged with Task IIB3.3*

IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.

IIB.4 Task 1: *Expand Network Communications – This task is closed.*

IIB.4 Task 2: *Conduct a study of random patient search simulations to test the efficacy of centralized contingency management.*

Period 5 Activity:

- NMDP provided support for donor/cord blood unit identification, selection and collection for the NIH intramural unrelated donor transplant program. Activity in the last quarter was as follows:
  - 1 PBSC and 1 Therapeutic T cell collection
- CIBMTR provided support for the rapid identification of potential donors for newly diagnosed AML patients under the following clinical trial protocol:
  - S1203: A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML)
  - CIBMTR provided study-specific sample collection kits for patients, processed samples, arranged HLA typing, and generated preliminary search strategy reports to assist in the identification of donors and/or CBU through the NMDP.
  - It is anticipated that 750 patients will be accrued in less than 5 years with 40% needing HLA testing and search strategy results. The trial opened in April 2013. Activity during the current quarter:
    - 73 patients enrolled in the study and 74 kits have been sent to patients (includes one replacement kit)
      - 73 kits were collected and returned to the repository
    - 20 patients were considered high-risk or unknown risk
    - 22 patients were HLA typed and 18 had a preliminary search completed

IIB.4 Task 3: *Benchmarking Analysis – This task is closed*
IIB.4 Task 4: *Expand Capabilities of Collection and Apheresis Centers – This task is closed.*

IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.
IIC.1 Task 1: *Continue to evaluate HLA disparity and impact on HSC transplantation by adding selected pairs to the Donor/Recipient Pair project utilizing sample selection criteria that optimize the new data generated by the typing project.*
Period 5 Activity: • No activity this period.

IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.
IIC.2 Task 1: *Continue to develop typing protocols for non-HLA immunogenetic loci, development of a lab network, enhancement of database to capture non-HLA data and continue analyses to evaluate genetic diversity in the transplant population.*
Period 5 Activity: • No activity this period.
IIC 2 Task 2: *Related Pairs Research Repository – This task is closed.*
IIC 2 Task 3: *CIBMTR Integration – This task is closed.*

IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

IID.1 Task 1: *Conduct observational research and interventional clinical trials.*

Period 5 Activity:

Cord Blood Research Subcommittee

Work continued on a study to assess CBU characteristics (viability, TNC, CFU and CD34) pre-freeze and post thaw.

- The data was submitted by the study cord blood banks.
- Data analysis was initiated and will be completed during the next quarter.

In the NMDP/Eurocord NIMA match case study it was shown that NIMA matches are associated with more common HLA types and therefore more common haplotypes. More common haplotypes may lead to better allele level matching and matching at HLA-C. Work was initiated and continued on a NIMA assessment of high resolution match grades at HLA-A, B, C, and DRB1 between transplant recipients and the cord blood unit to determine whether the NIMA phenomena may be a consequence of better allele level matching in the NIMA matched group.

- Analysis of the data was initiated and will be completed during the next quarter.

IID.1 Task 2: *Research with NMDP Donors – This task was merged with IID1.1.*

IID.1 Task 3:
Expand support for immunobiology research, statistical genetics and clinical research studies under CIBMTR Immunobiology Working Committee.

Period 5 Activity:

The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies. and held

- The annual IB working committee meeting was held during the BMT Tandem Meetings. The group discussed study progress and priorities and accepted seven new proposals for initiation in July 2014:

- *The prognostic impact of somatic mutations and levels of CXC chemokine ligands on post hematopoietic cell transplantation (HCT) outcomes in patients with myelodysplastic syndromes (MDS).* PIs: Wael Saber, Coleman Lindsley, Benjamin Ebert
- *Donor-Specific anti HLA antibodies, Allele and Antigen level HLA mismatches in the outcomes of Transplantation of Non-Malignant Diseases with Unrelated Donors.* PIs: Marcelo Fernandez-Vina and Ann Woolfrey
- *Structural/Functional Models of HLA for Data Mining of Permissive Mismatching in Allogeneic Hematopoietic Stem Cell Transplantation.* PI: Loren Gragert
- *Indirectly recognizable HLA epitopes (PIRCHES): a retrospective validation study on the role of indirect recognition of mismatched HLA in hematopoietic stem-cell transplantation outcome.* PI: Eric Spierings
- *A Retrospective Assessment of Outcomes of Follicular Lymphoma Patients who have Undergone Allogeneic Stem Cell Transplant Based on Human Leukocyte Antigen (HLA) Type.* PIs: Basem William, Marcos de Lima, Marcelo Fernandez-Vina and Brian Hill
- *Assessing the similarity of the T cell receptor repertoire in allogeneic hematopoietic stem cell recipients with the same single human leukocyte mismatches.* PI: Everett Meyer
- *mtDNA haplotypes and unrelated donor transplant outcomes.* PIs: Michael Verneris and Julie Ross

- Three abstracts were presented at the BMT Tandem Meetings:
  - Joseph Pidala, et al., *HLA-mismatch is associated with worse outcomes after myeloablative conditioning and unrelated donor hematopoietic cell transplantation: A CIBMTR analysis.* BMT Tandem 2014 annual meeting, oral presentation and received a Best Abstracts Award.
  - Shahinaz Gadalla, et al., *Donor telomere length predicts recipient survival after allogeneic hematopoietic cell transplantation in patients with bone marrow failure syndromes.* BMT Tandem 2014 annual meeting, oral presentation.
  - Hideki Nakasone, et al., *Sensitization to HY-antigen in female donors was not associated with the post-transplant HY-IgG development nor clinical outcomes in sex-mismatched transplantation.* BMT Tandem 2014 annual meeting, oral presentation.
- Six manuscripts were accepted or published:

- Katharina Fleischhauer, et al., *Risk-associations between HLA-DPB1 T cell epitope matching and outcome of unrelated hematopoietic cell transplantation are independent from HLA-DPA1.* Accepted in BMT
- Marcelo Fernandez-Vina, et al., *Identification of a permissible HLA mismatch in hematopoietic stem cell transplantation.* Published in Blood.
- Alan Howard, et al., *Evaluation of peripheral blood stem cell quality in products transported by traditional courier or commercial overnight shipping services.* Published in Transfusion.
- Sengsayadeth S, et al., *Cytotoxic T-Lymphocyte Antigen-4 (CTLA-4) Single Nucleotide Polymorphisms Are Not Associated with Outcomes after Unrelated Donor Transplant: A Center for International Blood and Marrow Transplant Research Analysis.* Published in BBMT.
- Gleason MK, et al., *CD16xCD33 bispecific killer cell engager (BiKE) activates NK cells from MDS patients against primary MDS and MDSC CD33+ targets.* Published in Blood.
- Cooley S, et al., *Donor Killer Cell Ig-like Receptor B Haplotypes, Recipient HLA-C1, and HLA-C Mismatch Enhance the Clinical Benefit of Unrelated Transplantation for Acute Myelogenous Leukemia.* Published in J Immunol.

ACRONYM LIST

AABB	American Association of Blood Banks	HML	Histoimmunogenetics Mark-up Language
AFA	African American	HR	High Resolution
AGNIS	A Growable Network Information System	HRSA	Health Resources and Services Administration
ABD	Antigen Binding Domain	HSC	Hematopoietic Stem Cell
AML	Acute Myelogenous Leukemia	IBWC	Immunobiology Working Committee
API	Asian Pacific Islander	ICRHER	International Consortium for Research on Health Effects of Radiation
AQP	Ancestry Questionnaire Project	IDM	Infectious Disease Markers
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IHWG	International Histocompatibility Working Group
ASBMT	American Society for Blood and Marrow Transplantation	IPR	Immunobiology Project Results
ASHI	American Society for Histocompatibility and Immunogenetics	IND	Investigational New Drug
ASTHO	Association of State and Territorial Health Officials	IS	Information Services
B-LCLs	B-Lymphoblastoid Cell Lines	IT	Information Technology
BARDA	Biomedical Advanced Research and Development Authority	IRB	Institutional Review Board
BBMT	Biology of Blood and Marrow Transplant	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BCP	Business Continuity Plan	KIR	Killer Immunoglobulin-like Receptor
BCPeX	Business Continuity Plan Exercise	MDACC	MD Anderson Cancer Center
BMCC	Bone Marrow Coordinating Center	MDS	Myelodysplastic Syndrome
BMDW	Bone Marrow Donors Worldwide	MHC	Major Histocompatibility Complex
BMT	Bone Marrow Transplantation	MICA	MHC Class I-Like Molecule, Chain A
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MICB	MHC Class I-Like Molecule, Chain B
BODI	Business Objects Data Integrator	MKE	Milwaukee
BRT	Basic Radiation Training	MRD	Minimal Residual Disease

C&A	Certification and Accreditation	MSKCC	Memorial Sloan-Kettering Cancer Center
CAU	Caucasian	MSP	Minneapolis
CBMTG	Canadian Blood and Marrow Transplant Group	MUD	Matched Unrelated Donor
CBB	Cord Blood Bank	NAC	Nuclear Accident Committee
CBC	Congressional Black Caucus	NACCHO	National Association of County & City Health Officials
CBS	Canadian Blood Service	NCBI	National Center for Biotechnology Information
CBU	Cord Blood Unit	NCBM	National Conference of Black Mayors
CDA	Clinical Document Architecture	NARR	National Alliance for Radiation Readiness
CFU	Colony Forming Unit	NCI	National Cancer Institute
CHORI	Children's Hospital of Oakland Research Institute	NDMS	National Disaster Medical System
CHTC	Certified Hematopoeitic Transplant Coordinator	NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
CIBMTR®	Center for International Blood & Marrow Transplant Research	NGS	Next Generation Sequencing
CIT	CIBMTR Information Technology	NHLBI	National Heart Lung and Blood Institute
CLIA	Clinical Laboratory Improvement Amendment	NIH	National Institutes of Health
CMCR	Centers for Medical Countermeasures Against Radiation	NIMA	Non-Inherited Maternal Antigen
CME	Continuing Medical Education	NIMS	National Incident Management System
CMF	Community Matching Funds	NK	Natural Killer
CMV	Cytomegalovirus	NLE	National Level Exercise
CNV	Copy Number Variation	NMDP®	National Marrow Donor Program
COG	Children's Oncology Group	NRP	National Response Plan
CREG	Cross Reactive Groups	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CSS	Center Support Services	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CT	Confirmatory Testing	OIT	Office of Information Technology
CTA	Clinical Trial Application	OMB	Office of Management and Budget

DC	Donor Center	ONR	Office of Naval Research
DHHS-ASPR	Department of Health and Human Service – Assistant Secretary Preparedness and Response	P2P	Peer-to-Peer
DIY	Do it yourself	PBMC	Peripheral Blood Mononuclear Cells
DKMS	Deutsche Knochenmarkspenderdatei	PBSC	Peripheral Blood Stem Cell
DMSO	Dimethylsulphoxide	PCR	Polymerase Chain Reaction
DoD	Department of Defense	PSA	Public Service Announcement
DNA	Deoxyribonucleic Acid	QC	Quality control
DR	Disaster Recovery	RCC	Renal Cell Carcinoma
D/R	Donor/Recipient	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
DSTU	Draft Standard for Trial Use	REAC/TS	Radiation Emergency Assistance Center/Training Site
EBMT	European Group for Blood and Marrow Transplantation	REST	Representational State Transfer
ED	Emergency Department	RFP	Request for Proposal
EDC	Electronic Data Capture	RFQ	Request for Quotation
EFI	European Federation of Immunogenetics	RG	Recruitment Group
EM	Expectation Maximization	RITN	Radiation Injury Treatment Network
EMDIS	European Marrow Donor Information System	SBT	Sequence Based Typing
ENS	Emergency Notification System	SCTOD	Stem Cell Therapeutics Outcome Database
ERSI	Environment Remote Sensing Institute	SG	Sample Group
FACT	Federation for the Accreditation of Cellular Therapy	SHF	Synthetic Haplotype Frequency
FBI	Federal Bureau of Investigation	SLCBB	St. Louis Cord Blood Bank
FDA	Food and Drug Administration	SLW	STAR Link® Web
FDR	Fund Drive Request	SSA	Search Strategy Advice
FLOCK	Flow Cytometry Analysis Component	SSO	Sequence Specific Oligonucleotides
FP	Filter Paper	SSP	Sequence Specific Primers
Fst	Fixation Index	SSOP	Sequence Specific Oligonucleotide Probes
GETS	Government Emergency Telecommunications Service	STAR®	Search, Tracking and Registry

GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SW	Buccal Swab
GIS	Geographic Information System	TC	Transplant Center
GS	General Services	TED	Transplant Essential Data
GTR	Genetic Testing Registry	TNC	Total Nucleated Cell
GvHD	Graft vs Host Disease	TP	Time Point
HCS®	HealthCare Standard	TSA	Transportation Security Agency
HCT	Hematopoietic Cell Transplantation	UCSF	University of California – San Francisco
HEPP	Hospital Emergency Preparedness Program	UI	User Interface
HHQ	Health History Questionnaire	UML	Unified Modeling Language
HHS	Health and Human Services	URD	Unrelated Donor
HIPAA	Health Insurance Portability and Accountability Act	WGA	Whole Genome Amplification
HIS	Hispanic	WMDA	World Marrow Donor Association
HLA	Human Leukocyte Antigen	WU	Work-up